IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No:	09/834,307
Title:	TARGETED THERAPEUTIC AGENT RELEASE DEVICES AND METHODS OF MAKING AND USING THE SAME
Applicant:	Richard J. Whitbourne *et al.*
Filed:	April 12, 2001
Confirmation No.:	3036
Art Unit:	1618
Examiner:	Micah Paul YOUNG
Atty. Dkt. No.:	32286-192724
Customer No.:	26694

PRE-APPEAL BRIEF REQUEST FOR REVIEW

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Commissioner for Patents
P.O. Box 1450
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Sir:

In response to the Final Office Action dated May 28, 2008, Appellant respectfully submits this Pre-Appeal Brief Request for Review pursuant to the "New Pre-Appeal Brief Conference Pilot Program" (1296 Off. Gaz. Pat. Office 67 (July 12, 2005), extended, 1303 Off. Gaz. Pat. Office 21 (February 7, 2006)). Appellant also submits herewith a Notice of Appeal pursuant to 37 C.F.R. § 41.31(a)(1), the claims having been finally rejected.

I. INTRODUCTORY REMARKS

Claims 23-67 and 69-83 are pending in the application and stand finally rejected. The Appellant believes, however, that the rejections set forth in the Final Office Action are improper based upon clear errors in fact and law, and the omission of essential elements for a prima facie rejection.

The pending claims relate to a medicated device and methods of making and using a medicated device, generally comprising a polymer/therapeutic agent coating that bridges from one edge or surface of an opening to another. (See independent claims 23, 43, 45, 50, 61, and

77.) In the Final Office Action, the Examiner maintained a rejection of all the claims under 35 U.S.C. § 103(a) as obvious in view of U.S. Patent No. 5,980,550 to Eder *et al.* ("Eder"). Eder does not, in fact, teach or suggest any coating bridging from one edge or surface of an opening to another. In finally rejecting the claims, the Examiner applied improper legal standards and failed to give due weight and consideration to the Declaration submitted to overcome the Examiner's incorrect interpretation of Eder. Applying proper standards, Eder does not support a prima facie rejection, and the evidence is sufficient to rebut a prima facie case of obviousness.

Accordingly, in view of the following remarks, the application is in condition for allowance, and reconsideration and withdrawal of the outstanding rejections are respectfully requested.

II. CLAIMS 23-52, 56-59, 61-65, 67, 69-71, 74- 76-78, AND 80-83

In numbered paragraphs 3-8 on pages 2-5 of the Final Office Action dated May 28, 2008, the Examiner maintains the rejection of claims 23-52, 56-59, 61-65, 67, 69-71, 74- 76-78, and 80-83 under 35 U.S.C. § 103(a) as being unpatentable over Eder in view of U.S. Patent No. 6,110,483 to Whitbourne *et al.* ("Whitbourne"). The rejection is respectfully traversed for at least the reasons presented in Section III on pages 11-15 of the Response filed February 22, 2008, hereby incorporated by reference. The arguments presented in Section III, and the evidence submitted in support thereof, were improperly ignored, and successfully rebut the Examiner's alleged *prima facie* case of obviousness, for numerous reasons, three of which are highlighted here: (1) The Examiner's position that Eder (in particular the cartoon of FIG. 2) teaches or suggests "a coating bridging from one edge or surface of the substrate to another across the opening" is simply incorrect. (2) The written disclosure of Eder is inconsistent with the Examiner's interpretation of FIG. 2. (3) The Chamberlain Declaration establishes how FIG. 2 should be read and defines non-obvious differences between the claimed invention and the cited references.

The Examiner improperly ignored evidence submitted by the Appellants

The Chamberlain Declaration, submitted under Rule 1.132 with the February 22, 2008 Response, includes a sketch of what cartoon/schematic FIG.2 of Eder, properly interpreted, teaches, and concludes that Eder did not show a bridging coating (*See* para. 6-8 and Appendix B). However,

on pages 7-9 of the Final Office Action, the Examiner clearly erred by improperly discrediting the "correct" schematic (Appendix B of the Chamberlain Declaration), stating that it "***has no bearing whatsoever on the patentability of the claims***." (emphasis added). Instead, ignoring the evidence in the Declaration to the contrary, the Examiner relied on a mistaken belief that Eder's FIG. 2 implicitly shows bridging.

The Examiner improperly gave NO weight to Appendix B of the Chamberlain Declaration. Such evidence cannot be completely disregarded. Opinion testimony is a form of evidence having probative value and must be given some weight. *See* M.P.E.P. § 716.01(c)(III). In this case, the "correct schematic" in Appendix B was based on a fair reading of Eder's entire disclosure by one familiar with the technology. *See* para. 8 of the Declaration. The Chamberlain declaration and Eder's disclosure itself both provide factual evidence that Eder did not teach or suggest a bridging coating. It is clear error for a decision on patentability to be made based without consideration of all the evidence, including evidence submitted by the applicant. *See* M.P.E.P. § 2142. Accordingly, when the Chamberlain Declaration is properly given its due weight, the so-called "correct schematic" does, in fact, bear on the patentability of the claims and demonstrates that the Examiner's interpretation of FIG. 2 of Eder is unreasonable and clearly erroneous. Reconsideration is respectfully requested.

The evidence establishes non-obviousness

On pages 6-7 of the Final Office Action, the Examiner states that the Chamberlain Declaration is "insufficient." The Examiner's analysis is clearly erroneous:

- *"The Declaration is not commensurate in scope with the instant claims and provides no direct actual comparison between the prior art."* (Final Office Action, p. 6.)

To the contrary, the declaration is commensurate in scope with the claims and does, in fact, directly compare the prior art and the claims. For example, in numbered paragraph 5 of the declaration, declarant Chamberlain points to claims 23, 43, 45, 50, 61, and 77 as reciting a coating "bridging" from one edge or surface to another across an opening. Then, in numbered paragraph 6, declarant Chamberlain outlines how and why Eder fails to teach or suggest any "bridging." Thus, the declaration is commensurate in scope with the claims and provides a direct comparison of the claims and Eder.

- *"The Declaration provides a theoretical schematic drawing showing what is alleged as actual "correct" interpretation of the Eder drawing. The Declaration presents no accompanying statement form the Eder inventors in support of this allegation, or any evidence to support this drawing other the opinions of the instantly named inventors. The arguments in the Declaration provide no solid evidence to support the proposed drawing."* (Final Office Action, pp. 6-7.)

This statement is wrong in many ways. First, the drawing provided in Appendix B of the Chamberlain Declaration is merely an illustration of the text of the Declarant's description of the Eder patent, to correct the improper reading by the Examiner. The Declaration provides ample "solid evidence to support the proposed drawing." Also, the entire disclosure of Eder provides further evidence to the same effect as the Chamberlain Declaration. See the February 22, 2008 Response, pp. 12-13 regarding the text of the Eder declaration. The Examiner's implied invitation to have the Eder inventors submit a declaration is based on another legal error – the correct standard is how a person of ordinary skill would read the reference, not what its authors intended. Finally, the Examiner is incorrect in concluding that the Chamberlain Declaration is by an inventor. Ms. Chamberlain is not a named inventor in this application.

- *"The Declaration also provides no comparison between the actual drawing or invention of the Eder patent and the invention of the instant claims."* (Final Office Action, p. 7.)

As noted above, paragraphs 5-6 of the Chamberlain Declaration provide a direct comparison and demonstrate the significant differences between the claims and the Eder reference.

In view of the foregoing, the Appellant respectfully submits that the Examiner committed clear error in failing to give the declaration due weight and consideration. Additionally, the Examiner misunderstood or failed to read the declaration fairly. The Appellant respectfully submits that the Chamberlain Declaration is, in fact, sufficient to rebut the Examiner's position as to what Eder reasonably teaches or suggests to one skilled in the art. Reconsideration is respectfully requested.

III. CLAIMS 50, 53-55, 60, 61, 66, 72-75, 77, AND 79

In numbered paragraphs 9-13 on pages 5-6 of the Final Office Action, claims 50, 53-55, 60, 61, 66, 72-75, 77, and 79 remain rejected under 35 U.S.C. § 103(a) as being unpatentable over the

proposed combination of Eder and Whitbourne, further in view of U.S. Patent No. 6,335,029 to Kamath *et al.* ("Kamath") and U.S. Patent No. 5,589,120 to Khan *et al.* ("Khan"). The rejection is respectfully traversed for at least the reasons set forth on page 15 of Appellant's response filed February 22, 2008, which is hereby incorporated by reference. In any event, claims 53-55, 60, 66, 72-75, and 79 depend variously from at least one of claims 23, 43, 45, 50, 61, and 77 and are, therefore, believed to be allowable for at least the same reasons set forth above. Reconsideration and withdrawal of the rejection are respectfully requested.

IV. INFORMATION DISCLOSURE STATEMENT

Additionally, the Appellant continues to respectfully request consideration of the Fifth Information Disclosure Statement (IDS) filed on April 18, 2007.

V. CONCLUSION

Claims 23-67 and 69-83 are pending in the application. In view of the foregoing remarks, the Appellant believes that the present application is believed to be in condition for allowance. If the Examiner believes, for any reason, that a personal communication will expedite prosecution of this application, the Examiner is hereby invited to telephone the undersigned at the number provided. Prompt and favorable consideration on the merits is respectfully requested.

Respectfully submitted,

Date: September 29, 2008

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